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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,099	10/31/2003	Dale B. Schenk	015270-006930US	7805

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,099	SCHENK ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9-13,54 and 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 9-13 and 54-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 7/8/2008. The status of the claims is as follows: claims 1, 3-6, 9-13 and 54-55 are under current examination.

The following objection or rejections have been withdrawn due to amendments of specification or claims:

1. Objection to the Specification;

2. 35 USC 112, 2nd paragraph (claim 54); and

3. 35 USC 112, 1st paragraph.

Additional search lead to the finding of new prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9-13 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Ueda et al (1993), US Patent Nos. 6416947, 5583112 and 6172122.

Ueda et al describe the 35-amino acid peptide NAC (see whole document). The authors describe the making of anti-NAC antibodies using 2 peptides dubbed X and Y used to raise rabbit antisera (see page 11283, RESULTS and DISCUSSION). Note that the authors also conjugated the peptides to keyhole limpet hemocyanin by using MBS (see page 11282, MATERIALS and METHODS). Thus, the authors provide a composition comprising NAC fragments which are conjugated and these conjugates are effective in eliciting an immunogenic response (i.e. antibody production). The authors do not describe using the adjuvants listed in claim 1 or manufacturing such a composition under good manufacturing practice.

US Patent 6416947 describes liposomes comprising an antigen and lipid A and that are adsorbed to aluminum hydroxide or alum (see whole document). Paragraphs 2 and 3 under DETAILED DESCRIPTION provide that antibody activity can be enhanced by 800-fold or more with the inventions and that it is generally expected that a vaccine prepared in accordance with Good Manufacturing Practices ("GMP") prescribed by the U.S. Food and Drug Administration will be less potent than one prepared otherwise. This expectation holds true for the above-described vaccine. Yet, the reduction in potency of the vaccine within the present

invention is much less than that of a vaccine that comprises the antigen alone adsorbed to aluminum hydroxide.

US Patent 5583112 describes the immunogen activity of the saponin conjugates and saponin adjuvants, including QS-21 also known as QA-21 (see Detailed Description). See paragraph 14 under Description of the Preferred Embodiments which recites the following: The increase in titer of antibody against a particular antigen upon administration of the vaccines and/or adjuvants of the invention may be used as a criteria for immunogenic activity (Dalsgaard, K. (1978) Acta Veterinia Scandinavica 69:1-40, Scott et al. Int. Archs. Allergy Appl. Immun. 77:409-412 (1985)). Briefly, one such test involves injecting CD-1 mice intradermally with a saponin/antigen conjugate which may be mixed with varying amounts of a potential adjuvant. Sera was harvested from the mice two weeks later and tested by ELISA for anti-immunogen antibody. Note that the adjuvants are filtered including through a 0.2 mu nylon mesh (see Example 1) and this is taught throughout the disclosure. Thus, QS-21 is a known adjuvant which leads to an increase in antibody titer.

US Patent 6172122 provides the following recitation with respect to Good Manufacturing Practice: In order for the compositions of this invention to be suitable for certain uses, compliance with FDA Good Manufacturing Practice (GMP) regulations (21 CFR Part 110) is

required. GMP regulations specify a means to assure a clean product which is of purity suitable for its intended use, does not transmit biological disease agents and avoids adulteration. The regulations list specific and general requirements on cleanliness and suitability of personnel, utensils and equipment, operations, grounds and facilities and measures to insure that processing controls are adequate. It is common practice for manufacturers to meet GMP with documented standard operating procedures (SOP) and check-lists and control charts to indicate compliance with the SOP on an hourly or daily basis, or on each batch as required.

It would have been obvious to one of ordinary skill in the art to combine the teachings above and make the claimed composition. One would have been motivated to do so in order to increase antibody titers by known adjuvants, including alum and QS-21, to NAC fragment. One would have also been motivated to abide by the GMP regulations to insure a purity suitable for its use as suggested above. Further, the prior art teaches that GMP can lead to a reduction in potency of the composition and adjuvants may overcome this reduction. There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used by the ordinary artisan. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648